

**REMARKS**

Applicants request favorable reconsideration of this application in view of the foregoing amendments and the following remarks. Of claims 1-34 that were pending in the application, claims 6, 7, 9-12, 15-18, 20, and 23-25 remain withdrawn from consideration and claims 1, 13, 14, 19, 21, 22, and 26-34 were rejected in the Office Action. By way of this Amendment, Applicants have amended independent claims 1, 14, 22, and 26. Claims 1-5, 8, 13, 14, 19, 21, 22, and 26-34 are respectfully submitted for further consideration.

Applicants appreciate the allowance of claims 2-5 and 8. Further, Applicants note that the rejection of claims 30-32 was likely inadvertent as these claims depend from allowed claims 2-4, respectively.

**1. Rejections of Claims 1, 13, 14, 19, 21, 22, 26-29, 33, and 34**

The Examiner rejected: (a) claims 1, 13, 14, 21, 22, 26, and 28-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 2,699,166 (“Dickenson”); and (b) claims 19 and 27 under 35 U.S.C. § 103(a) as allegedly being obvious when considering Dickenson in view of U.S. Patent No. 6,010,478 (“Bellhouse-I”). Preliminarily, as previously mentioned, the rejection of claims 30-32 appears to have been inadvertent and, therefore, the aforementioned rejection of these claims under § 102(b) will not be addressed. Accordingly, Applicants will address, and respectfully traverse, these rejections with respect to claims 1, 13, 14, 19, 21, 22, 26-29, 33, and 34.

As discussed in previous responses, Applicants note that as the instant application was filed as a PCT on July 6, 1998 and as Bellhouse-I issued thereafter on January 4, 2000, Bellhouse-I does not qualify as prior art under 35 U.S.C. § 102(b). Further, as Bellhouse-I is not “by another,” Bellhouse-I also fails to qualify as prior art under 35 U.S.C. § 102(e). Applicants note that the gas fluid to which the Examiner cited in Bellhouse-I was previously disclosed in WO94/24263 (“Bellhouse-II) and in its related U.S. Patent No. 5,630,796 (“Bellhouse-III”). Bellhouse-II and Bellhouse-III were submitted in the Information Disclosure Statement (“IDS”) filed on July 26, 2003, which the Examiner acknowledged in the Office Action mailed April 22, 2004. As Bellhouse-II was published on October 27, 1994 and as Bellhouse-III issued on May 20, 1997, these references may qualify as prior art under 35 U.S.C. § 102(b). For ease of comparison, however, the rejection will be addressed, and respectfully traversed, with respect to Bellhouse-I.

As amended herein, claim 1 (*i.e.*, the claim from which claims 13 and 29 depend) recites a capsule that includes, among other possible things (italic and underline emphasis added):

a first member and  
a second member,

*wherein said capsule is adapted for containing a dose of particles to be delivered within a pressurized fluid flow,*

wherein said first and second members are coupled together to provide a closed pocket within the members for containing the dose,

*wherein one of said first and second members is configured to slide relative to the other member when an external portion of said capsule is contacted with the pressurized fluid flow, and*

*wherein said first and second members are constructed and arranged such that upon said relative movement a passage is formed through said capsule and said pocket is opened to expose the dose of particles for entrainment in the pressurized fluid flowing through said passage.*

Similarly, as amended herein, claim 14 (*i.e.*, the claim from which claims 19, 21, and 33 depend) recites a syringe for delivering a dose of particles within a pressurized fluid flow. This syringe includes, among other possible things (italic and underline emphasis added):

- (a) an upstream portion which is interfaced with a source of fluid under pressure;
- (b) a downstream nozzle portion;
- (c) an intermediate portion arranged between the upstream and downstream portions, wherein said intermediate portion comprises first and second members which are coupled together to provide a closed pocket within the members for containing the dose of the particles, and further *wherein one of said first and second members is configured to slide relative to the other member*; and
- (d) an actuator mechanism for initiating a flow of fluid from the source of fluid to the intermediate portion *whereby pressure exerted by the fluid causes one of said first and second members to move relative to the other member*, said first and second members being constructed and arranged such that upon said relative movement a passage is formed through said intermediate portion and said pocket is opened *to expose the dose for entrainment in the fluid flowing through said passage and into the downstream nozzle portion.*

As amended herein, claim 22 (*i.e.*, the claim from which claim 34 depends) recites a syringe for delivering a dose of particles within a pressurized fluid flow. This syringe includes, among other possible things (italic and underline emphasis added):

- (a) an upstream portion which is interfaced with a source of fluid under pressure;
- (b) a downstream nozzle portion;

- (c) an intermediate portion arranged between the upstream and downstream portions, wherein said intermediate portion comprises first and second members which are coupled together to provide a closed pocket for containing the dose of the particles, and further wherein one of said first and second members is configured to slide relative to the other member; and
- (d) an actuator mechanism for initiating a flow of fluid from the source of fluid to the intermediate portion *whereby pressure exerted by the fluid causes one of said first and second members to move relative to the other member*, said first and second members being constructed and arranged such that upon said relative movement a passage is formed through said intermediate portion and said pocket is opened *to expose the dose for entrainment in the fluid flowing through said passage and into the downstream nozzle portion*,

wherein the closed pocket is pre-filled with the dose of the particles and said first and second members are sealably coupled together, and

wherein the fluid is a compressible gas.

Similarly, as amended herein, claim 26 (*i.e.*, the claim from which claims 27 and 28 depend) recites a capsule that includes, among other possible things (italic and underline emphasis added):

a first member and  
a second member,  
*wherein said capsule is adapted for containing a dose of a therapeutic agent to be delivered within a pressurized fluid flow*,  
wherein said first and second members are coupled together to provide a closed pocket within the members for containing the dose,  
*wherein one of said first and second members is configured to slide relative to the other member when an external portion of said capsule is contacted with the pressurized fluid flow*, and  
*wherein said first and second members are constructed and arranged such that upon said relative movement a passage is formed through said capsule and said pocket is opened to expose the dose of the therapeutic agent for entrainment in the pressurized fluid flowing through said passage*.

For at least the following reasons, Dickinson and Bellhouse-I (standing alone or combined) fail to teach or suggest the capsules recited in claims 1 and 26 or the syringes recited in claims 14 and 22.

Dickinson teaches an ampule 17 and a stopper 20 (which the Examiner refers to as a “second member”), which form a pocket. A sack 37 (which the Examiner refers to as a “first member”) surrounds the ampule 17. In use, liquid pressure is applied to the sack 37, thereby causing the ampule 17 to slide along an annular groove 41. As the stopper 20 remains stationary, the movement of the ampule 17 causes liquid medicament provided within the pocket to be expelled via an outlet 38. At no time during use of Dickinson’s device,

however, does the fluid that pushes against the sack 37 come into contact (and deliver) the medicament within the pocket. In contrast, claims 1, 14, 22, and 26 recite that the same pressurized fluid flow: (a) causes one of the first and second members to slide relative to the other member; and (b) delivers the dose of particles/therapeutic agent. For this reason alone, Dickinson fails to teach or suggest the above-italicized limitations of claims 1, 14, 22, and 26.

Dickinson also fails to teach or suggest two members that form a “closed pocket” and that satisfy the other limitations of these claims. Specifically, the Examiner asserts that Dickinson’s sack 37 and stopper 20 are analogous to the first and second members recited in claims 1, 14, 22, and 26. These members 20, 37, however, fail to define a “closed pocket.” Specifically, the second member (stopper 20) contains a hole therethrough that is created by a cannula 39 that is driven through the second member (stopper 20) when a cap 43 is mounted on the retaining ring 44. *See* Dickinson at col. 3, lines 9-14, 62-65. As a result of the hole through the second member (stopper 20), the pocket formed by the first and second members 37, 20 is, contrary to the above-underlined limitations of claims 1, 14, 22, and 26, open, *i.e.*, the pocket is not “closed,” as above-italicized in each of these claims.

Even assuming, *arguendo*, that Bellhouse-I were capable of curing the second of the aforementioned deficiencies of Dickinson (*i.e.*, assuming Bellhouse-I taught a closed pocket formed by two members), Bellhouse-I clearly fails to cure Dickinson’s first deficiency. Moreover, the Examiner already acknowledged this shortcoming of Bellhouse-I during the Examiner Interview on October 17, 2005, during which the Examiner agreed that Bellhouse-I failed to teach or suggest two members, one of which was configured to slide relative to the other member. As Bellhouse-I fails to teach or suggest such relative sliding movement, Bellhouse-I also fails to teach or suggest delivering particles (or a therapeutic agent) with a pressurized fluid that also caused the relative sliding movement.

In light of the foregoing, it is clear that Dickinson and Bellhouse-I (standing alone or combined) fail to teach or suggest at least the above-italicized limitations of claims 1, 14, 22, and 26. Accordingly, Dickinson and Bellhouse-I can not be used to reject claims 1, 14, 22, and 26, or any claim dependent thereon, under 35 U.S.C. §§ 102(b), 103(a). Moreover, as claims 13 and 29 depend from claim 1, as claims 19, 21, and 33 depend from claim 14, as claim 34 depends from claim 22, and as claims 27 and 28 depend from claim 26, each of these dependent claims is also allowable over Dickinson and Bellhouse-I, without regard to the other patentable limitations recited therein. Accordingly, a withdrawal of the various rejections of claims 1, 13, 14, 19, 21, 22, 26-29, 33, and 34 is both warranted and respectfully requested.

**2. Previously Withdrawn Claims**

As withdrawn claims 10-12 depend from allowable claim 1, as withdrawn claim 9 depends from allowed claim 2, as withdrawn claims 6 and 7 depend from allowed claim 4, and as withdrawn claims 15-18, 20, and 23-25 depend from allowable claim 14, each of these dependent/withdrawn claims is also allowable. Accordingly, when issuing a Notice of Allowance, the Examiner is requested, under 37 C.F.R. § 1.141 and M.P.E.P. § 809.04, to reenter and allow claims 6, 7, 9-12, 15-18, 20, and 23-25.

**CONCLUSION**

For the aforementioned reasons, claims 1-34 are now in condition for allowance. A Notice of Allowance at an early date is respectfully requested. The Examiner is invited to contact the undersigned if such communication would expedite the prosecution of the application.

Respectfully submitted,

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY ADDITIONAL FEES WHICH MAY BE REQUIRED REGARDING THIS APPLICATION UNDER 37 C.F.R. §§ 1.16-1.17, OR CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 19-0741. SHOULD NO PROPER PAYMENT BE ENCLOSED HEREWITH, AS BY A CHECK BEING IN THE WRONG AMOUNT, UNSIGNED, POST-DATED, OTHERWISE IMPROPER OR INFORMAL OR EVEN ENTIRELY MISSING, THE COMMISSIONER IS AUTHORIZED TO CHARGE THE UNPAID AMOUNT TO DEPOSIT ACCOUNT NO. 19-0741. IF ANY EXTENSIONS OF TIME ARE NEEDED FOR TIMELY ACCEPTANCE OF PAPERS SUBMITTED HEREWITH, APPLICANT HEREBY PETITIONS FOR SUCH EXTENSION UNDER 37 C.F.R. § 1.136 AND AUTHORIZES PAYMENT OF ANY SUCH EXTENSIONS FEES TO DEPOSIT ACCOUNT NO. 19-0741.